

In the United States Court of Federal Claims

No. 98-817 V
(Filed July 23, 2008)

ENRIQUE M. ANDREU, a minor)
child by his parents and natural)
guardians, ENRIQUE C. ANDREU)
and SONIA C. ANDREU,)
Petitioners,)
v.)
)
SECRETARY OF THE)
DEPARTMENT OF HEALTH AND)
HUMAN SERVICES,)
Respondent.)

ORDER^{1/}

Petitioners, Enrique C. Andreu and Sonia C. Andreu seek review and reversal of the Special Master's May 29, 2008 Decision on Remand denying their petition for compensation under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 to 34 ("Vaccine Act"). Petitioners assert that the genesis of their son Enrique's seizures, which initially occurred on November 1, 1995, was a diphtheria, tetanus, and whole-cell pertussis ("DPT") vaccination he was administered on October 31, 1995.

The respondent, Secretary of the Department of Health and Human Services, requests that the Special Master's Remand Decision denying compensation be sustained.

^{1/} Petitioners have fourteen days to request redaction of any material "that includes medical files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision, while not published, will be available on the court's website. 42 U.S.C. § 300aa-12(d)(4)(B).

With respect to the function of this court, the Vaccine Act provides:

(2) Upon the filing of a motion [to review a special master's decision], the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2).

The Vaccine Act establishes the standard for recovery of compensation as follows:

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

42 U.S.C. § 300aa-13(a).

Of relevance to this case, 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) provides that for recovery of compensation, the petitioners must have demonstrated by a preponderance of the evidence on the record as a whole, that Enrique “sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A)”^{2/}

The relevant record on which the causation decision was rendered in this matter consists of: medical records and literature; testimony at an August 27, 1999 “onset” hearing before Special Master Abell from witnesses Sonia C. Andreu, Enrique C. Andreu, Eric Andreu, and Jesus A. Gutierrez and pre-hearing affidavits from these witnesses; testimony at a November 3, 2006 “causation” hearing before Successor Special Master Vowell from petitioners’ expert witness, Dr. Carlo Tornatore and respondent’s expert witness, Dr. Joel Herskowitz; and testimony at an April 28, 2008 remand hearing from treating physicians Dr. Trevor J. Resnick and Dr. Marcel J. Deray.

The successor special master’s initial decision on August 29, 2007, concluded that petitioners “failed to show that Enrique’s seizures were caused by his DPT vaccination on October 31, 1995.” (Slip op. (Aug. 29, 2007) at 41). Petitioners filed a Motion for Review taking issue with this conclusion.

Following briefing and oral argument an order was issued on March 3, 2008, remanding the matter to the successor special master for reconsideration and to obtain, to the extent possible, testimony from Enrique’s treating physicians to assist in this task.

Testimony from Drs. Resnick and Deray was then added to the record and, on reconsideration, the successor special master ruled “I conclude that they [petitioners] have failed to demonstrate the logical connection between vaccine and injury in this

^{2/} Subparagraph (A) refers to the Vaccine Injury Table. DPT is listed in this table. *See* 42 U.S.C. § 300aa-14. An injury meeting the relevant criteria in the table is presumed to be caused by the vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Petitioners initially pleaded that Enrique’s seizures were covered by the table so that causation was presumed, but also plead actual causation. *See* Petition ¶¶ 11, 16, filed October 26, 1998. Petitioners subsequently withdrew their table injury claim and rely on the record to claim actual vaccine causation. *See* Tr. 58 (Nov. 3, 2006).

case, and thus adhere to my initial opinion that the petition for compensation must be denied.” (Slip op. (May 29, 2008) at 16).

A review of the record of the proceedings, upholds the successor special master’s conclusion to deny compensation. The conclusion is not “[a]rbitrary, capricious, an abuse of discretion or otherwise not in accordance with law” 42 U.S.C. § 300aa-12(e)(2)(B). The successor special master noted that “[t]he clear failure in petitioners’ case was their inability to draw the logical connection, required by *Althen*, between the postulated mechanism of injury and the clinical evidence in this case.” (Slip op. (May 29, 2008) at 14).

In *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), the court ruled that to prove causation-in-fact, petitioners must establish by preponderant evidence that the vaccine brought about the injury by showing: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.”

Petitioners, through the testimony of Dr. Tornatore, set forth a medical theory asserted to causally connect the DPT vaccination Enrique received on October 31, 1995, with the onset of his seizures on November 1, 1995, within the proximate temporal relationship for DPT causation. This theory essentially proposes that the toxins present in whole-cell pertussis vaccine, in bloodstream circulation after vaccine administration, can cross into the brain causing behavioral changes, such as unusual crying, and depending on the extent of injury to the brain, seizures. (Tr. 29-33, 73-83 (Nov. 3, 2006).)

Respondent’s expert, Dr. Herskowitz did not dispute the biologic plausibility of Dr. Tornatore’s medical theory, but seriously questioned its application to explain Enrique’s seizures in the absence of evidence of serious brain injury or atrophy. (Tr. 185-88, 196-97 (Nov. 3, 2006).) The addition of testimony from Drs. Deray and Resnick served to support Dr. Herskowitz’s view on the inapplicability of petitioners’ medical theory. Both treating physicians testified that test results relied upon by Dr. Tornatore as showing brain injury or atrophy did not. (Tr. 30, 34-35, 59-61 (April 28, 2008).) Dr. Resnick’s order to avoid pertussin in Enrique’s future vaccinations, which Dr. Tornatore relied upon as supporting causation, was explained by Dr. Resnick as comprising only a precautionary measure and not one premised upon any

belief in causation. (Tr. 52-53 (April 28, 2008).) Dr. Resnick, the initial treating physician, testified that because Enrique did not suffer from other symptoms expected with DPT-related seizures such as fever, irritability, or change in behavior, the cause for Enrique's seizures was unknown. (Tr. 46-47, 65-66 (April 28, 2008).) Enrique's medical records showed normal development until January of 1998, when his seizures became intractable and uncontrolled by medication. (Pet. Ex. 3-7 (pp. 1-2), 12 (pp. 4-5).) Developmental delay was not noted until September of 1998. (Pet. Ex. 15 (pp. 46-47).)

In summary, the clinical evidence of record concerning Enrique's seizures does not show the extent of initial injury sufficient to validate petitioners' medical theory of DPT causation.

The record confirms that Dr. Deray considers Enrique's seizures to have a DPT connection. His view is based on the temporal association of the onset of seizures, the fact that no other cause was established and his view that medical literature supports a connection. (Pet. Ex. 22; Tr. 21-22, 36-38 (Apr. 28, 2008).) Dr. Deray is correct that a temporal association exists and that no other cause has been established or proposed in these proceedings. To the extent that medical literature has relevance, however, the material of record does not support a connection between afebrile seizures, such as Enrique experienced initially, and DPT vaccination. A temporal association between a vaccination and an injury such as present here, is, by itself, insufficient to establish causation-in-fact. *Althen v. Sec'y of HHS*, 418 F.3d at 1278; *Hodges v. Sec'y of HHS*, 9 F.3d 958, 960-62 (Fed. Cir. 1993). Dr. Deray did not set forth a medical theory causally connecting the vaccination and Enrique's seizures. In these circumstances, Dr. Deray's evidence does not supply the requisite support to establish causation-in-fact.

Accordingly, the evidence of record fails to support the application of Dr. Tornatore's medical theory of causation in the clinical situation experienced by Enrique, and no other theory was proposed. Thus aside from any issue concerning credibility of witnesses, as discussed at some length by the successor special master, the preponderant evidence simply did not establish a medical theory causally connecting Enrique's October 31, 1995 vaccination with the afebrile focal seizures suffered by Enrique commencing on the next day but followed by a substantial period

of normal development before intractable seizures occurred.^{3/} In this circumstance the successor special master's conclusion denying compensation is correct, as the establishment of a causally connecting medical theory is a prerequisite for recovery of compensation.

As it is concluded that the successor special master was not arbitrary or capricious, did not abuse discretion or otherwise violate law in ruling that petitioners' have not met the burden of proof to establish causation-in-fact, as set forth in *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1324 (Fed. Cir. 2006); and *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2909 (2007), it is **ORDERED** that the decision on remand, filed May 29, 2008, is **SUSTAINED**. Judgment shall be entered accordingly.

s/ James F. Merow

James F. Merow

Senior Judge

^{3/} The Vaccine Act requires that the determination of preponderance of the evidence must be made "on the record as a whole." 42 U.S.C. § 300aa-13(a)(1). Thus in determining preponderance, the entire record must be considered, not just the evidence submitted by one party. If respondent is confident that the record does not encompass a preponderance of evidence supporting compensation, there is no requirement to address whether an injury is "due to factors unrelated to the administration of the vaccine. . . ." 42 U.S.C. § 300aa-13(a)(1)(B); *Bradley v. Sec'y of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).